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10/521,886	07/05/2005	Robert Kopesky	60282-USA	8844
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			EXAMINER	
			BLAND, LAYLA D	
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			1609	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/521,886

Applicant(s)

KOPESKY ET AL.

Examiner

Layla Bland

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1609

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

This application is a national stage entry of International Application PCT/US03/22988 and claims priority to U.S. Provisional Application No. 60/398,903. Claims 1-31 are pending in this application and are examined on the merits herein.

Claim Objections

Claim 1 is objected to because of the following informalities: there is no period at the end of the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 and 4-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and dependent claims 2, 3, and 8-31 recite the limitation "elevated temperature." "Elevated" is a relative term and renders the claim indefinite because it is impossible to determine the temperature range intended to be claimed. For the purposes of examination, "elevated" is interpreted to mean a temperature above room temperature.

Claims 4-7 include the limitation "at least about," which is a relative term and renders the claims indefinite. The term is not defined by the claim, the specification

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does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-17, 20, 22-24, 26 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanna, et al. (U.S. 6,228,213 B1, May 8, 2001) in view of Schaible, et al. (WO 01/05441 A1, January 11, 2001) and Trusovs, et al. (U.S. 6,392,034 B1, May 21, 2002).

Hanna, et al. teach a process for the production of microcrystalline cellulose by reactive extrusion. The process involves feeding cellulose into an extruder with a barrel. Acid and cellulose-containing material (pure cellulose can be used) are premixed and fed through the extruder or simultaneously fed into the extruder [column 3, lines 34-39]. Preferably, the temperature of the extruder barrel is about 80°C to 200°C, and most preferably 140°C [column 3, lines 60-65]. Different heating regimes affect the resulting particle size of the product and particles smaller than 200 microns can be created [column 5, lines 57-58]. The measured level-off degree of polymerization varies with the starting material and is 220 for wood-cellulose microcrystals [column 5, lines 66 and 67 and column 6, lines 1-3]. The cellulose is

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pressurized by the screw of the extruder and is hydrolyzed by acid. The ratio of acid solution to cellulose is approximately 1:1 [column 4, lines 19-22]. The extrusion is preferably a continuous process [column 4, lines 8-9] and results in reaction times which are shorter than conventional methods [column 4, lines 22-25]. After extrusion, the cellulose product is washed, bleached, and dried [column 2, lines 56-64]. The product can be bleached with hydrogen peroxide [column 4, lines 44-46]. After being bleached, the product is dried by spray drying [column 4, lines 55-60]. The microcrystalline cellulose can also be manufactured using a twin screw extruder [column 5, lines 32-33].

Hanna, et al. do not teach a process for producing microcrystalline cellulose using an active oxygen compound. Hanna, et al. are silent on the exact pressure used in the method, the pH of the reaction mixture and the residence time of the extrusion.

Schaible, et al. teach a process for the production of microcrystalline cellulose comprising hydrolyzing pulp with active oxygen [see abstract]. Specific examples of active oxygen compounds include hydrogen peroxide [page 6, line 15]. The method simultaneously hydrolyzes and bleaches the starting material to obtain a high grade microcrystalline cellulose product [page 2, lines 20-24]. The reaction can be performed under increased temperature and pressure, the optimization of which can be ascertained by one skilled in the art [page 7, fourth paragraph]. The method of Schaible, et al. results in microcrystalline cellulose having a degree of polymerization as low as 208 [Example 17].

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Trusovs, et al. teach a method of producing microcrystalline cellulose comprising the addition of hydrogen peroxide. Hydrogen peroxide depolymerizes the substrate and reduces viscosity [column 2, lines 49-54].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use reactive extrusion with hydrogen peroxide to produce microcrystalline cellulose. The skilled artisan would have been motivated to do so with an expectation of success because the extruder method has a shorter reaction time than conventional methods and the use of hydrogen peroxide for hydrolysis also bleaches the material at the same time, so there is no need for a separate bleaching step. It is considered within the skill of one of ordinary skill in the art to optimize parameters such as pressure, time, concentration, and order of addition of reagents. The pH of the reaction mixture during extrusion is an intrinsic feature of the solvents and reagents used in the reaction. Because hydrogen peroxide is known to depolymerize cellulose under standard reaction conditions (Trusovs, et al.), it is considered obvious to hold the reaction mixture after shearing to further depolymerize the material.

Claims 18-21, 25-27 and 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanna, et al. (U.S. 6,228,213 B1, May 8, 2001) in view of Schaible, et al. (WO 01/05441 A1, January 11, 2001) and Trusovs, et al. (U.S. 6,392,034 B1, May 21, 2002) as applied to claims 1-17, 22-24 and 28 above, and further in view of McGinley, et al. (U.S. 5,192,569, March 9, 1993).

Hanna, et al., Schaible, et al., and Trusovs, et al. teach as set forth above.

Hanna, et al., Schaible, et al., and Trusovs, et al. do not teach attriting the microcrystalline cellulose product or the addition of an additive.

McGinley, et al. teach the production of colloidal grades of microcrystalline cellulose by attriting the wetcake after filtration and washing steps, at which time additives such as sodium carboxymethylcellulose (a barrier dispersant) can be added [column 4, lines 63-69]. The attrited, colloidal microcrystalline cellulose may then be dried [column 5, lines 1-3]. Microcrystalline cellulose can be used with other cellulosic materials such as carboxymethylcellulose to form a water-dispersible colloid for use as a stabilizing agent and to enhance the texture of foods [column 1, lines 48-54].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to produce attrited, dried microcrystalline cellulose and to add an additive to the product. The skilled artisan would have been motivated to do so with an expectation of success in order to create a colloidal product which can be used as a food additive, as taught by McGinley, et al.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one

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of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Bland whose telephone number is (571) 272-9572. The examiner can normally be reached on M-R 8:00AM-5:00PM UST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ldb


JANET L. ANDRES
SUPERVISORY PATENT EXAMINER

